Document Title: THROMBOELASTOGRAPH (TEG)
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Approval Signature	Approval Date
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REVISION HISTORY

Procedure #	Revision Date	Reason for Revision
SH.CP.AU.hem.0123.0002	10/12/2015	Updated to include new QC schedule included with the IQCP
SH.CP.AU.hem.0123.0003	9/2/2016	Inclusion of reagent storage and transport stability
SH.CP.AU.hem.0123.0004	5/16/2018	Correction of Establishment of Tolerance Limits. Addition of Critical Values Adjustment of LY30 normal range

PROCEDURE TITLE: THROMBOELASTOGRAPH (TEG)

I. PURPOSE

This procedure details the use of the Haemoscope Thromboelastograph (TEG®) Hemostasis analyzer including: quality control, sample collection, patient testing, result interpretation, instrument maintenance, and troubleshooting. Coagulation tests are obtained to ensure accurate assessment of patient hemostasis. The TEG® Instrument System records the process of blood coagulation, including fibrinolysis. It measures *in vitro*, the kinetics of clot formation and dissolution by a mechanical process that monitors very low shear elasticity changes.
The TEG® System, comprised of the TEG® Hemostasis Analyzer and the TEG® Analytical Software, is designed to perform a whole blood coagulation test that produces a hemostasis profile. The TEG® Hemostasis Analyzer automatically records the viscoelastic changes in a sample of whole blood, plasma or platelet-rich plasma as the sample clots, retracts and/or lyses. The resultant profile is a measure of the kinetics of clot formation and dissolution of clot quality (the ability to perform the work of coagulation). Because the TEG® system monitors shear elasticity (a physical property), it is sensitive to all the interacting cellular and plasmatic components in the blood that may affect the rate or structure of a clotting sample and its breakdown. The overall profile can be qualitatively or quantitatively interpreted in terms of the normal, hypo, or hypercoagulable state of the sample, the degree of lysis, and other measurements of coagulopathy.

To evaluate the information displayed by the graphic output, six parameters of clot formation are measured:

- **R**: The time from when the sample is put into the TEG® Analyzer until the first sign of clot formation (amplitude of 2 mm) is reached.
- **K**: The time from the R, or beginning of clot formation, to a fixed level of clot firmness (amplitude of 20 mm) is reached.
- **Angle** (α): The rate of clot growth.
- **MA** (Maximum Amplitude): Maximum strength or stiffness (maximum shear modulus) of the developed clot. MA measures the strength of the clot.
- **LY30:** a measure of clot retraction/ lysis, 30 minutes after MA has been detected.
- **CI**: R, K, Angle, and MA are combined to yield a Coagulability Index (CI) that describes the patient's overall coagulation status.

A series of additional measurements are generated to evaluate clot retraction, lysis, etc., and are fully described in the TEG® User Manual.

II. SCOPE

This procedure will be used by technologists of the UR Medicine Labs Hematology-Chemistry lab to perform the standard Thromboelastograph (TEG).

III. RESPONSIBILITIES

Roles	Responsibilities
Quality	Ensure that procedure is followed when performing the TEG test.
Medical Director	Approval of the TEG test procedure.
Management	Ensure that procedure is followed when performing the TEG test.
Technologists	Follow procedure.

IV. ACRONYMS

URMC	University of Rochester Medical Center
SMH	Strong Memorial Hospital
TEG	Haemonetics Thromboelastograph Hemostasis Analyzer

V. SPECIMENS

A. Citrated Whole Blood Specimen

Citrated whole blood is the preferred sample when there is a potential for a delay (>4-6 min after collection) in starting the testing on the TEG® Analyzer.
Analysis of citrated whole blood samples must wait at least 15 minutes after collection, but must be started within 2 hours of specimen collection.

B. Unacceptable specimens

1. Any clotted or under-filled Sodium Citrate tubes are unacceptable.
2. Samples received greater than 2 hours after collection.

VI. QUALITY CONTROL

A. IQCP: This Individualized Quality control Plan (IQCP) has been established by the URMC Hematology Lab to meet all regulatory and manufacturer's requirements. Quality control procedures are performed to assure the accuracy and precision of the test system as well as Technologist technique.

- Internal Quality Control system:

  An eTest will be performed on all channels every 8 hours to ensure the proper electronic functioning of each channel on the TEG analyzers.

- External Quality Control system:

- Two control materials of different concentrations (Level 1 and Level 2) shall be run once every 24 hours on each channel that will be used for patient testing, for daily validation of instrument and operator performance.

- Performance of external QC will be scheduled as follows:

  1. Channels 1 and 2: Day shift
  2. Channels 3 and 4: Evening shift
  3. Channels 5 and 6: Night shift

- Run 2 levels of Controls whenever the instrument has been serviced, moved, or recalibrated, and whenever a new lot or shipment of reagents is received.

B. Daily maintenance and setup tasks: perform prior to beginning QC analysis

1. The TEG® Analyzer(s) should always be on. If not, turn on the TEG® Analyzer by pressing the green power switch. Allow the temperature for all channels to reach 37°C ±0.5°. Note that the temperature can be adjusted for each column individually, if needed. (See User's Manual section "Setting the Temperature" for information on how to set the temperature of the columns.)

2. Make sure the cup wells are clean and dry. Clean with cotton swab and alcohol if needed.

3. Open the TEG® software: user name: "operator", there is no password. Sign in at the log in screen using your user id and password.

4. Check the instrument leveling bubble and adjust, if not level, by turning the level adjustment legs under the TEG® Analyzer in the front and back.

5. Perform a baseline e-test. Raise all carriers and move levers to the "test►" position. Access the e-test menu by selecting [Options] from the menu bar at the top of the home screen. From the drop down menu, select [Maintenance]. Perform the e-test by following the prompts on the screen.
   a. For a given channel, select the channel, and then click on [eTest]. Wait until the message "eTest value is OK" is issued.
   b. If the eTest value is "off center", turn the screw on the back of the instrument labeled BASE for that channel. Continue to repeat the test and make adjustments until the values under "Min" and "Max" are close to the target of 2000. Range is 1950-2050.
   c. Hit [Done] to go back to the main screen.
   d. Return the levers to "load" position.
   e. After completion of the above procedures, the TEG® Analyzers are ready to run Quality control.

6. Discard expired reagents. **DO NOT USE EXPIRED QC REAGENTS!**

7. When reagents are opened, date and initial the container and indicate new expiration date. Record date shipment was opened in the TEG Reagent log. Controls expire 2 hours after reconstitution.

8. Enter new QC ranges into the TEG workstation when lot numbers change. Note: Control lot numbers, expiration dates, date reagent was changed, and QC results will be documented in the QC database on the TEG workstation. Take corrective action for any unacceptable results (see pg 6).

C. **Reagent QC Analysis-** Level I Normal and Level II Abnormal Controls

Control Lot numbers:

The master lot number is the actual lot number. Ex: Level1= 1022-1201

The HMO number is specific to a shipment of controls. This includes the water and $CaCl_2$ in each kit. If a new HMO number is not in the drop down list of Sample Descriptions, it can be typed in manually.

1. If refrigerated, remove control materials and allow them to sit for 10 min to equilibrate to room temperature.

2. Tap the vial to get all the lyophilized material to the bottom.

3. Remove the cap and slowly pour or pipette the contents of the 1 mL vial of distilled water supplied with the kit into the control vial. Replace the cap.

4. Allow 15-20 minutes for adequate rehydration, with occasional agitation. **Controls must be run within two hours after reconstitution.**

5. **Run both the Level I Normal and Level II Abnormal Quality Controls every 24 hours on each channel that will be used for patient testing. Refer to pg. 3 for QC schedule**
   Note: One vial of QC is enough to test both channels on one TEG® Analyzer.

6. Press 

to enter TEG® screen.

7. Enter the Sample type (ST) and patient ID information for each channel to be tested.

8. Select the first channel that will be tested. It will turn blue.

9. Load the clear disposable cups and pins for each TEG® column. (See Procedure pg7 for Loading Cups and Pins.)

10. Pipette 20 µl of .2M calcium chloride (included in the biological control kit) into each TEG® cup.

11. Pipette 340 µl of reconstituted control into the first channel, raise carrier, move lever to test, press F10. The channel will turn green to indicate “active” status, and the cursor will move to the next channel.

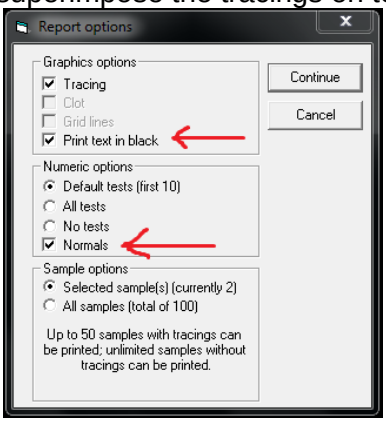
12. Repeat step 11 for all channels being analyzed with QC material.

13. Once all channels have been started, you may return to the main screen by clicking


14. Terminate controls after 20 minutes or when the asterisk no longer appears next to the MA results, by pressing 

or F11. All 4 parameters must be finalized for the QC to be considered valid.

15. Verify that the final results of each of the parameters are within the manufacturer's ranges for each parameter.
16. If any QC parameters are out of range, repeat with fresh QC material. If failure continues, do not use that channel and notify supervisor of QC failure.
17. Print QC reports once each level has run on both channels. Press [Multi]. Select the 2 tracings for L1 or L2, press [Done]. Two tracings will appear, press [Super] to superimpose the tracings on top of each other. Press [Report] [Continue] [Print].



Reports can be placed in the QC review bin next to printer L29.

18. Document the completion of the daily QC for each channel on the daily maintenance log kept at the TEG workstation.

D. Establishment of tolerance limits:

When a new lot or shipment (HMO) of QC material is received, 12 vials (1 box) of each level will be tested using all 3 instruments. The result data for all 3 instruments is merged and analyzed. Ranges of +/- 2SD are established for R, K, Angle, and MA. Once the new material is "in use" results outside these ranges are unacceptable and must be repeated.

Do not perform patient testing unless quality control testing is acceptable. Failure to obtain the expected values for **all four** parameters (R, K, angle, and MA) for Level 1 and Level 2 may be an indication of product deterioration, TEG® instrument or procedural problems.

E. QC Failures

1. If either the normal or abnormal control is out of range, **do not use the instrument to test or report any patient results until the controls are within the specified ranges.**
2. Check the temperature. If the temperature appears correct, re-run using fresh vial of the control and fresh calcium chloride.
3. If the results are still out of range, contact Haemoscope technical support.
4. Document any out of range quality control corrective action in the QC remarks log in the QC database on the workstation. The V4 software will prompt the user to enter a corrective action remark**.**
5. Controls outside the acceptable limits should be brought to the attention of the supervisor (or designee).

6. Whenever the QC has failed, a “Warning sign” (stating that the QC has failed and that the analyzer should not be used) should be placed on the channel.

VII. SPECIAL SAFETY PRECAUTIONS

- The Standard Universal Precautions recommended by the Centers for Disease Control should be followed whenever blood or body fluids are handled. These precautions include wearing gloves (and other personal protective equipment, if appropriate).
- Dispose of collection equipment and specimens in a proper biohazard waste according to SMH Infection Control Policies.
- Always use puncture resistant containers for sharps such as needles and biohazard bags/boxes for non-sharps.
- Refer to Material Safety Data Sheets/Safety Data Sheets in SDS Manual for safety information.

VIII. MATERIALS

A. Equipment

- **Thromboelastograph® Whole Blood Hemostasis Analyzers, Model 5000**
  - Quantity - 3

B. Supplies

- **Disposable Cups and Pins for the 5000 series**: Haemoscope Corporation, Catalog No. 6211. Store at room temperature.
- **Disposable Heparinase I Cups and Pins for the 5000 series:** 2 International Units (IU) of lyophilized Heparinase I. The amount of enzyme in each cup should be sufficient to reverse 6.0 IU of heparin/mL of blood,
  Haemoscope Corporation, Catalog No. 6212. Store at 2º-8ºC.
- Pipettes and Pipette tips for delivering 20, 340, and 1000µL
- Sodium Citrate blue topped tubes containing 0.5 ml of 3.2% (0.105 M) Sodium citrate (pH 7.4).

C. Reagents

- **Kaolin, Premeasured:** Haemoscope Corporation, Catalog No. 6300.
  The Kaolin vials are stored at 2º-8ºC until use.
- **TEG® Biological Controls:** Haemoscope Corporation.
  Level I Catalog No. 8001, Store at 2º-8ºC.
  Biological (bovine plasma and platelets) control products: 12 vials (1 mL) of normal, 12 vials (1 mL) of distilled water, 1 vial (1 mL) of $CaCl_2$
  Level II Catalog No. 8002, Store at 2º-8ºC.
  Biological (bovine plasma and platelets) control products: 12 vials (1 mL) of abnormal, 12 vials (1 mL) of distilled water, 1 vial (1 mL) of $CaCl_2$
  1. Unopened vials stable to date on package when stored at 2-8°C.
  2. Reconstituted vials are stable for 2 hours at room temperature.
  3. Dispose of used vials in biohazard container.
- **Calcium Chloride (0.2M):** Haemoscope Corporation, Catalog No. 7003;
  Store at 2º-8ºC.

- **Handling and Storage Instructions:**
  Recommended long term storage is between 2ºC and 8ºC.

When stored between 2°C and 8°C, the product has a shelf life up to the date labeled on the box.

Recommended long term storage outside of recommended storage temperature:

Internal studies have shown that if storage temperatures are as low as -20°C or as high as 25°C (77°), product can be stored for up to one month. Reagent stability cannot be assured if the product is stored beyond one month, below -20°C or above 25°C, and they should not be used.

Transport

Shipping stability for the product has been established per ISTA 7D "Summer Profile" testing with an extended hold time to simulate 72 hours of summer shipping in temperatures up to 35ºC (95°F) plus 96 hours of warehouse storage at 30ºC.
The limited amount of time the product could be exposed to elevated and sub-optimal temperatures during transport is considered unlikely to reduce product stability.

IX. PROCEDURE

A. Loading cups and pins

1. Determine if plain or Heparinase (blue) cups and pins are required. Blue cups are to be used when HTEG is ordered.
2. With the lever in the load position, slide the carrier half way down the rails.
3. Load a disposable cup and pin in the cup well. (Do not touch the outside of the pin or the inside of the cup.)
4. Grasping from the sides, carefully slide the carrier all the way up, being sure that the disposable pin is standing straight up in the cup so that the skewer tip can enter smoothly.
5. With the top of the carrier flush with the bottom of the column, stabilize the analyzer with your hand on top, and firmly push the pin into place using the pusher button located at the bottom of the carrier.
6. Lower the carrier and make sure that the pin is correctly loaded by checking that the bottom tip of the skewer is touching the inside bottom of the disposable pin.
7. Slide the carrier halfway back down and push the cup firmly into the cup well. The cup should rest flush with the carrier and should not pop up.
8. Repeat for up to 6 samples to be run simultaneously**.**

B. Entering Patient Information

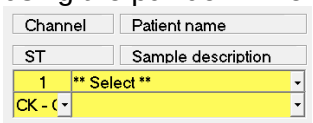
1. Patient's identity should be confirmed using 2 identifiers. Acceptable identifiers include first and last name, medical record number, and date of birth.

2. **Before a patient may be run, a new case must be created.** Press the → 

"Select case mode" window will appear. Verify "Add case" is selected and press [Done]. In the "Create case" window, enter patient MRN, last and first name, press [Done]. This patient will now be available in step 5.

3. In the 

screen, select the channel to be used and enter the following data by using the pull down menus.



4. **Sample Type (ST):** This presents a drop down list of pre-defined types. For standard TEG select “CK” for a Citrated, Kaolin-Activated, Whole Blood sample, or “CKH” (when patient is being treated with heparin, the blue heparinase cups and pins should be used).

5. **Patient Name:** selectable from drop down menu once a case is created

6. **Sample description:** Use this entry to identify the specimen:
   - Collection date, time, Order number

   ex: 6/22/15 06:23 D822XXXX

7. Repeat for up to 6 samples to be run simultaneously.

C. Loading the sample

1. Verify the cursor is in channel 1. It will automatically move to the next channel when each patient is started.

2. Pipette 20µl of calcium chloride into each loaded TEG® cup.

3. Pipette 1ml of citrated blood from the blue top tube to the vial containing kaolin. Cap and mix by inversion five times. Be sure to coat the inside of the kaolin vial with blood to ensure proper mixing.

4. Pipette 340µl of blood from the kaolin vial into the TEG® cup.

5. While the lever is still in the Load position, raise the carrier up carefully until it is flush with the bottom of the column. Move the lever to the Test position.

6. Quickly press [F10] on the keyboard or click 

to begin the test.

7. If you have followed the sample loading procedure correctly, the sample information display for that channel number changes from white to green. Channels that are color-coded green are active, yellow are inactive channels (even if an inactive channel is selected, turning it blue, the channel number will remain either yellow for inactive or green for active in this screen).

8. Once you have started a sample on the TEG® Analyzer, you can return to the main screen and view its progress by double clicking the graph or selecting a channel and then clicking the 

button.

9. If the channel does not activate, call Haemonetics technical support.

10. Monitor the tracing for critical results. At 15 minutes a critical R Time, and possibly Angle and MA will be identifiable. After this, it is acceptable to wait for the end of the test to identify additional critical values. See **Critical results** and **RESULT REPORTING** for information on identifying and notifying physicians of critical values. Critical R time caused by Heparin is the only result that requires rerunning the sample.

11. The instruments are set to terminate once LY30 has been calculated. The sample information display for that channel number will change from green to yellow. This also helps distinguish between active and terminated (or "completed") channels on the "Main" screen.

12. Slide the lever to the left to the "Load" position and then press down on the lever to eject the pin.

13. Slide the carrier down to the platform. Be sure the pin has dropped into the cup.

14. Press the carrier down firmly against the platform. This will depress the pusher button and release the cup from the carrier.

15. To print final results, press 

, select [Continue] when "Report options" window appears (desired options should be pre-selected) [Print]. Final results should be printed and given to the clinician responsible for interpretation (Dr. Refaai, Dr. Schmidt, or Coagulation resident).

X. LIMITATIONS

A. Evaluation of test results

1. Any test tracings that do not show the formation of a clot should be considered beyond clinical significance. Verify the correct database is in use and obtain a new specimen from the patient immediately for a repeat.
2. Test results should always be scrutinized in light of a specific patient's condition or anticoagulant therapy. Any test result exhibiting inconsistency should be repeated or supplemented with additional test procedures.

B. Sources of error

1. Traumatic sampling of blood will reflect the trauma of the phlebotomy and not coagulation of the patient. A discard tube is recommended when collecting a blood sample. The discard tube is discarded because it is contaminated with tissue thromboplastin or, if it comes from an indwelling line, it is contaminated with heparin or stagnant blood. If the blood sample is difficult to draw because the needle or catheter is against the vessel wall, the endothelium may release plasminogen activators or prostacylins, which can also produce artifacts on the TEG® tracing.
2. TEG5000® instruments are very sensitive to vibration. This will present as a wavering tracing and may cause the instrument difficulty in calculating results. Disturbing the table should be avoided.
3. Delay in starting the test (F10) after adding the sample to the cup will falsely decrease the R time. The reaction begins the instant blood is added to the cup but, the instrument doesn't start measuring it until the test is "started".

C. Interfering substances

The TEG® test may be affected by hemodilution, cardioplegia solutions, hypothermia, platelet dysfunction, hypofibrinogenemia, other coagulopathies, and certain medications. Test results that do not agree with expected values should be verified and thereafter evaluated by alternative diagnostic mean

XI. CALCULATIONS

The Thromboelastograph® Analytical Software run on an IBM compatible Pentium computer will perform all calculations.

XII. RESULT INTERPRETATION

A. TEG Parameters

Each TEG® parameter, R, K, angle, MA, and LY30, represents a different aspect of the patient's hemostasis.

- **R:** The time of latency from the time measurement is started until the initial fibrin formation (measured at 2mm). R is prolonged by anticoagulants and is shortened by hypercoagulable states.

- **K:** K is a measure of the speed to reach a clot strength of 20 mm.

- **Angle:** Measures the rapidity (kinetics) of fibrin build-up and cross-linking, that is the speed of clot strengthening. The angle is more comprehensive than K. Angle is decreased by anticoagulants that affect fibrinogen and platelet function.

K and **angle** both measure similar information and both are affected by the availability of fibrinogen, which determines the rate of clot buildup; in the presence of factor XIII, which enables cross-linking of fibrin to form a stable clot; and to a lesser extent, by platelets. Therefore, an elongated K and reduced angle represent a low level of fibrinogen (factor XIII is rarely deficient) and can be corrected by administering cryo or FFP, which have both. K is prolonged by anticoagulants that affect fibrinogen and platelet function.

- **MA:** (Maximum Amplitude) - A direct function of the maximum dynamic properties of fibrin and platelet bonding and represents the ultimate strength of the fibrin clot.

  MA is affected by platelet number and function and, to a lesser extent, by fibrinogen level. However, MA and (K, angle) are correlated due to the interaction between fibrinogen level and platelets which together form the fibrin-platelet bonding to produce the final clot. Therefore, there is a compensated effect between fibrinogen level and platelets.

  In case of cardiac surgery when MA is small, infusion with platelets alone may correct the coagulopathy in most cases because platelets are affected by most, if not all, cardiac surgical procedures.

- **LY30:** Measures the rate of amplitude reduction 30 minutes after MA is reached and represents the ultimate stability of the clot. LY30 greater than 7.5% represents hyperfibrinolysis.

- **CI: (Coagulation Index)** - Linear combination of R, K, angle, and MA. Positive values (CI > +3.0) indicate the sample is hypercoagulable. Negative values (CI < -3.0) indicate that the sample is hypocoagulable.

B. QUALITATIVE INTERPRETATION — PATTERN RECOGNITION

Normal
R;K;MA;Angle=Normal

Anticoagulants/hemophilia
Factor Deficiency
R;K = Prolonged
MA;Angle = Decreased

Platelet Blockers
Thrombocytopenia/Thrombocytopathy
R ~ Normal; K = Prolonged
MA = Decreased

Fibrinolysis
R ~ Normal;
MA = Continuous Decrease

Hypercoagulation
R;K = Decreased
MA;Angle = Increased

D.I.C.
Stage 1 - Hypercoagulable state with secondary fibrinolysis

State 2 - Hypocoagulable state

C. Reference Range

Normal values for Citrated Kaolin Whole Blood Samples with or without heparinase cup:

- R= 4-10 min
- K = 1-3 min
- Angle = 53-73 degrees
- MA= 50-72 mm
- LY30 = 0-8.0%

D. Critical Results

- R > 12 minutes
- Angle < 40 degrees
- MA < 40 mm
- LY30 > 10%

E. Post-protamine

Looking at the R parameter, if the sample with heparinase and the sample without are the same, the patient has received enough protamine to reverse heparin.

If both tracings are normal and the patient is bleeding, the reason may be surgical.

If the R without heparinase is elongated and the heparinase tracing is normal and the patient is bleeding, the bleeding is due to excess of heparin.

If the tracing with heparinase shows a coagulopathy, the patient is treated accordingly. Most likely coagulopathies will be consistent with those observed during the monitoring while the patient is on the pump. For confirmation of treatment, it is recommended to run the TEG® within 10-15 minutes post-treatment administration.

XIII. RESULT REPORTING

- Enter results into SOFT and save. A second tech must check for transcription errors and Verify results. Print an “Instant Report” to include when results are submitted for interpretation. The LIS may add a preliminary interpretation comment to the results based on the value entered.
- A hardcopy of the TEG results should be printed and attached to the Instant Report, then submitted for review to Dr. Refaai, Dr. Schmidt, or the Coagulation resident.
- Remote viewing of the tracings is accessible with Information Systems Division permission.

A. CRITICAL RESULTS:

- Please check on the TEG tracing regularly. At 15 minutes, a critical R Time, and possibly Angle and MA will be identifiable. After this, it is acceptable to wait for the end of the test to identify additional critical values. As soon as a critical R time is identified, it must be called. Be sure to verify the patient is not receiving heparin. If they are, repeat test using Heparinase. All available critical values are to be reported and documented during this call.
- Any additional critical values that occur after the first call can be called upon test completion.
- Reporting Critical Results to Physicians:
  Follow SH.CP.AU.gen.0020, Results Reporting Procedure Critical Value Notification.

XIV. TRAINING

Role	Training Needed
Testing Personnel	Competency Assessment
Trainer	Competency Assessment

To verify that an employee can perform a test according to procedure:

- Review Procedure and Procedural Checklist, a step-by-step description of the test general guidelines of operation.
- Complete demonstration of test by performing QC and/or patient test under the supervision of a qualified trainer. Document training on appropriate training documentation form and retain in employee file.
- Re-certification is required for all trained operators to assess competency, semiannually the first year of testing and annually thereafter.

XV. REFERENCES

A. Haemoscope Thromboelastograph® Coagulation Analyzer User Manual, 1999.

B. TEG® 5000 Hemostasis System Operator Training Workbook ML1043, 2006.

C. Haemonetics internal document reference number: TR-SHP-100181: Refrigeration Statement: May 2012

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